



*Producers of Quality  
Nonprescription Medicines and  
Dietary Supplements for Self-Care*

## CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

*Formerly Nonprescription Drug Manufacturers Association*

May 6, 1999

Debra L. Bowen, M.D.  
Deputy Director, Office of Drug Evaluation V  
Acting Director, Division of OTC Drug Products  
Division of OTC Drugs Products (HFD-560)  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

RE: Docket No.: 98N-0337: Request for a Feedback Letter  
Concerning the Use of Columns for and within the Drug  
Facts Box

Dear Dr. Bowen:

Thank you for providing us with a briefing on the new OTC label content and format Final Rule at the April 23, 1999 Feedback Meeting. As an organization that has followed this matter for many years, we focused our comments on sharing our concerns with the Final Rule in terms of the potential large number of exemptions that might be submitted were there to be no further consideration of possible category exemptions or possible further step-wise modifications of the Modified Format.

Based on the feedback we received during the meeting, we sense that your team is willing to have further dialogue on this matter. Because the Final Rule has a number of features that were not in the Proposed Rule, it is necessary that we test drive all aspects of the Final Rule to ensure that any further information and data submitted to the agency is an accurate representation of the practical application of the Final Rule to date. We plan a detailed submission that will explain a suggested approach to addressing the problems we've encountered with the Final Rule and our reasons for that suggested approach. To do this effectively, we need immediate feedback from the agency on the matter of column format.

Specifically, we believe that the spirit and intent of the Final Rule can be met with the use of a column format under the Warnings heading or the use of the column format for the entire Drug Facts labeling section

continued ...

98N-0337

C1

Enclosed are the following mock-up labels that demonstrate our point.

- A Sudafed 24's carton for a blister pack: Use of columns for sections following Uses;
- B Sudafed 24's carton for a blister pack: Use of columns in the Warning section;
- C NyQuil Liquicaps Multi-symptom Cold/Flu Relied: Use of columns for Drug Facts information;
- D Preparation H Cream 9 oz: No columns with overflow text;
- E Preparation H Cream 9 oz: Use of columns for the Drug Facts Box, in order to avoid excessively long printed lines, which would diminish label readability. Columns allow all the information to fit with no overflow.

The use of columns is a significant space saver. Use of columns definitely allows the Standard Format and the Modified Format to be used for more SKU's, thereby helping to limit the number of potential exemptions. While we show examples of the two-column format, we understand that certain labels in long rectangular boxes can appropriately accommodate three columns without unreasonable compression of the printed material. We note that the Supplement Facts label allows the use of columns.

**ACTION REQUESTED:** It is vital that we have a very quick turnaround on this issue, as the compliance clock is running and companies have to make formatting decisions in preparing our response to you. Please call me at your earliest convenience to provide us with your direction in this area. A follow-up feedback letter affirming the ability to use columns for and within the Drug Facts Box is our objective on this aspect of the Final Rule.

Thank you.

I look forward to your early response.

Sincerely yours,



R. William Soller, Ph.D.  
Senior Vice President and  
Director of Science & Technology

cc: Dockets Management Branch Docket No. 98N-0337  
Cazemiro R. Martin  
CHPA Label Coordinators  
Thomas Donegan, Esq., CTFA

Enclosures: As stated

WS/jq:S&T/jquaempts/LABELING/FDAletCOLUMNSmay6

Final Register 3-17

**Sudafed C&A (4-6-99)**

Version-6 CONDENSED font

2 columns-back panel only

More Bullets on a line,  
2 em spacing between.

Drug Facts- 7.1 pt Helv Bold Italic

Headings- 7 pt Helv Bold Italic

Sub heads- 6 pt Helv Bold

Text- 6 pt Helv Regular, 1/2 pt leading

2.5 pt outline box

2.5 pt barline

0.5 pt hairline

| Drug Facts   |                    |
|--|--------------------|
| <b>Active ingredient (in each tablet)</b>  | <b>Purpose</b>     |
| Pseudoephedrine HCl 60 mg  | Nasal decongestant |
| Chlorpheniramine maleate 4 mg  | Antihistamine      |
| <b>Uses</b> temporarily relieves these symptoms due to the common cold or hay fever (allergy rhinitis)<br>■ runny nose ■ sneezing ■ itchy, watery eyes ■ itchy throat ■ nasal congestion   |                    |
| <b>Warnings</b><br><b>Do not use</b> if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.<br><b>Ask a doctor before use if you have</b><br>■ heart disease ■ high blood pressure<br>■ thyroid disease ■ diabetes ■ glaucoma<br>■ trouble urinating due to an enlarged prostate gland ■ a breathing problem such as emphysema or chronic bronchitis<br><b>Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives</b><br><b>When using this product</b><br>■ do not use more than directed<br>■ you may get drowsy ■ avoid alcoholic drinks ■ excitability may occur, especially in children ■ alcohol, sedatives and tranquilizers may increase drowsiness<br>■ be careful when driving a motor vehicle or operating machinery |                    |
| <b>Stop use and ask a doctor if</b><br>■ you get nervous, dizzy, or sleepless<br>■ symptoms do not get better within 7 days or occur with a fever<br><b>If pregnant or breast-feeding, ask a health professional before use.</b><br><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.   |                    |
| <b>Directions</b><br>■ take every 4 to 6 hours<br>■ do not take more than 4 doses in 24 hours<br>adults and children 12 years and over 1 tablet<br>children 6 years to under 12 years 1/2 tablet<br>children under 6 years ask a doctor  |                    |
| <b>Inactive ingredients</b> candelilla wax, croscopolvone, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, poloxamer 407, polyethylene glycol, polyethylene oxide, pregelatinized corn starch, silicon dioxide, sodium lauryl sulfate, stearic acid, and titanium dioxide.   |                    |

Store at 59° to 77° in a dry place

**SUDAFED**  
COLD & ALLERGY  
24 TABLETS



3 0000-0000-00 3

FACE PANEL

LOT & EXP AREA

Dist: WARNER-LAMBERT  
CONSUMER HEALTHCARE  
Morris Plains, NJ 07950 USA  
©1996 Warner-Lambert  
Questions? Call toll-free  
1-800-223-0182.

Final Register 3-17

**Sudafed C&A** (4-6-99)

Version-7 CONDENSED font

2 columns with  
Actives, Uses, Directions & Inactives  
copy across the panel

2 em spacing between.

Drug Facts- 7.1 pt Helv Bold Italic

Headings- 7 pt Helv Bold Italic

Sub heads- 6 pt Helv Bold

Text- 6 pt Helv Regular, 1/2 pt leading

2.5 pt outline box

2.5 pt barline

0.5 pt hairline

|   |              |   |                                       |          |                                    |            |                        |              |
|---|--------------|---|---------------------------------------|----------|------------------------------------|------------|------------------------|--------------|
| <b>Drug Facts</b><br><b>Active ingredient (in each tablet)</b><br>Pseudoephedrine HCl 60 mg<br>Chlorpheniramine maleate 4 mg  |              | <b>Purpose</b><br>Nasal decongestant<br>Antihistamine |                                       |          |                                    |            |                        |              |
| <b>Drug Facts (continued)</b><br><b>Uses</b> temporarily relieves these symptoms due to the common cold or hay fever (allergy rhinitis)<br>■ runny nose ■ sneezing ■ itchy, watery eyes ■ itchy throat ■ nasal congestion   |              |   |                                       |          |                                    |            |                        |              |
| <b>Warnings</b><br><b>Do not use</b> if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.<br><b>When using this product</b><br>■ do not use more than directed<br>■ you may get drowsy ■ avoid alcoholic drinks<br>■ excitability may occur, especially in children ■ alcohol, sedatives and tranquilizers may increase drowsiness<br>■ be careful when driving a motor vehicle or operating machinery<br><b>Stop use and ask a doctor if</b><br>■ you get nervous, dizzy, or sleepless<br>■ symptoms do not get better within 7 days or occur with a fever<br><b>If pregnant or breast-feeding</b> , ask a health professional before use<br><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away. |              |   |                                       |          |                                    |            |                        |              |
| <b>Ask a doctor before use if you have</b><br>■ heart disease ■ high blood pressure<br>■ thyroid disease ■ diabetes ■ glaucoma<br>■ trouble urinating due to an enlarged prostate gland ■ a breathing problem such as emphysema or chronic bronchitis<br><b>Ask a doctor or pharmacist before use if you are</b> taking tranquilizers or sedatives  |              |   |                                       |          |                                    |            |                        |              |
| <b>Directions</b><br>■ take every 4 to 6 hours<br>■ do not take more than 4 doses in 24 hours<br><table border="0"> <tr> <td>adults and children 12 years and over</td> <td>1 tablet</td> </tr> <tr> <td>children 6 years to under 12 years</td> <td>1/2 tablet</td> </tr> <tr> <td>children under 6 years</td> <td>ask a doctor</td> </tr> </table>  |              |   | adults and children 12 years and over | 1 tablet | children 6 years to under 12 years | 1/2 tablet | children under 6 years | ask a doctor |
| adults and children 12 years and over   | 1 tablet     |   |                                       |          |                                    |            |                        |              |
| children 6 years to under 12 years  | 1/2 tablet   |   |                                       |          |                                    |            |                        |              |
| children under 6 years  | ask a doctor |   |                                       |          |                                    |            |                        |              |
| <b>Inactive ingredients</b> candelilla wax, croscovidone, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, poloxamer 407, polyethylene glycol, polyethylene oxide, pregelatinized corn starch, silicon dioxide, sodium lauryl sulfate, stearic acid, and titanium dioxide  |              |   |                                       |          |                                    |            |                        |              |

**SUDAFED**  
COLD & ALLERGY  
24 TABLETS

3 0000-0000-00 3

Proof of Purchase

**FACE PANEL**

**LOT & EXP AREA**

Div. WARNER-LAMBERT  
 CONSUMER HEALTHCARE  
 Morris Plains, NJ 07950 USA  
 © 1996 Warner-Lambert  
 Questions? Call toll-free  
 1-800-223-0182.

**COPY PER THE RULE  
NO SPACE ACCOUNTED FOR UPC**



5 15/32"

1"

5/8"

**Drug Facts (continued)****Warnings**

For external use only

Ask a doctor before use if you have ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes  
 ■ difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression

**When using this product**

■ do not exceed the recommended daily dosage  
 ■ do not put into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if ■ bleeding occurs ■ condition worsens or does not improve within 7 days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- before applying, remove protective cover from dispensing cap.
- attach dispensing cap to tube. Lubricate dispensing cap well, then gently insert dispensing cap part way in the anus.
- thoroughly cleanse dispensing cap after each use and replace protective cover.
- adults and children over 12 years of age: When practical, cleanse and gently dry the affected area by patting or blotting with an appropriate cleansing tissue before applying gel
- apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement

DRUG FACTS

PREPARATION H®

**PREPARATION H®**  
 HEMORRHOIDAL  
**CREAM**

**Prevents Further Irritation**

HELPS SHRINK SWELLING OF  
 IRRITATED HEMORRHOIDAL TISSUES

GIVES PROMPT TEMPORARY RELIEF  
 FROM THE PAINFUL BURNING, ITCHING  
 AND DISCOMFORT OF HEMORRHOIDS

NET WT .9 OZ (26 g)

**Drug Facts****Active ingredients**

Glycerin 12%  
 Petrolatum 18%  
 Phenylephrine HCl 0.25%  
 Shark liver oil 3.0%

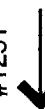
**Purposes**

.....protectant  
 .....protectant  
 .....vasoconstrictor  
 .....protectant

**Uses** ■ temporarily shrinks hemorrhoidal tissue  
 ■ temporarily relieves itching, burning and discomfort



Read Direction  
 #1251



PharmaCode Area  
 (UNVARNISHED AREA)

OVERFLOW TEXT

**Drug Facts (continued)**

- apply externally or in the lower portion of the anal canal only
- children under 12 years of age: ask a doctor

**Inactive ingredients** BHA, carboxymethylcellulose sodium cetyl alcc  
 lanolin, methylparaben, propylene gallate, propylene glycol, propylparabe  
 alcohol, tocopherol, xanthan gum, water

Whitehall-Robins Healthcare, Madison, NJ 07940 Made in USA

2867-10/DRUG

LOT & EXP. DATE  
 (UNVARNISHED AREA)

D

5 15/32"

1"

5/8"

#### Drug Facts (continued)

##### When using this product

- do not exceed the recommended daily dosage
- do not put into the rectum by using fingers or any mechanical device or applicator

##### Stop use and ask a doctor if

- bleeding occurs
- condition worsens or does not improve within 7 days

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

#### Drug Facts (continued)

##### Other information

- Store in cool place or at room temperature but not over 80°F
- Tamper-Evidence: Do Not Use if outer wrap imprinted "PREPARATION H" is broken or missing.

PREPARATION H

#### DRUG FACTS

PREPARATION H

#### Drug Facts

##### Active ingredients

Glycerin 12%.....protectant  
Petrolatum 18%.....protectant  
Phenylephrine HCl 0.25%.....vasoconstrictor  
Shark liver oil 3.0%.....protectant

##### Uses

- temporarily shrinks hemorrhoidal tissue
- temporarily relieves itching, burning and discomfort

#### Warnings

##### For external use only

- Ask a doctor before use if you have
- heart disease
  - high blood pressure
  - thyroid disease
  - diabetes
  - difficulty in urination due to enlargement of the prostate gland
- Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression

#### Directions

- before applying, remove protective cover from dispensing cap.
- attach dispensing cap to tube. Lubricate dispensing cap well, then gently insert dispensing cap part way in the anus.
- thoroughly cleanse dispensing cap after each use and replace protective cover.
- adults and children over 12 years of age: When practical, cleanse and gently dry the affected area by patting or blotting with an appropriate cleansing tissue before applying gel
- apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- apply externally or in the lower portion of the anal canal only
- children under 12 years of age: ask a doctor

**Inactive ingredients** BHA, carboxymethylcellulose sodium cetyl alcohol, citric acid, edelate disodium, glyceryl oleate, glyceryl stearate, lanolin, methylparaben, propylene gallate, propylene glycol, propylparaben, simethicone, sodium benzoate, sodium lauryl sulfate, stearyl alcohol, tocopherol, xanthan gum, water

2867-100RUG

Whitehall-Robins Healthcare, Madison, NJ 07040 Made in USA

#### Prevents Further Irritation

HELPS SHRINK SWELLING OF  
IRRITATED HEMORRHOIDAL TISSUES

GIVES PROMPT TEMPORARY RELIEF  
FROM THE PAINFUL BURNING, ITCHING  
AND DISCOMFORT OF HEMORRHOIDS

NET WT .9 OZ (26g)



PharmaCode Area  
(UNVARNISHED AREA)



LOT & EXP. DATE  
(UNVARNISHED AREA)



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r's **R. William Soller, Ph.D.** Phone **202 429-9260**

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To Recipient's Name **Dockets Management Branch** Phone **301 827-6860**

Company **Food and Drug Administration**

Address **5630 Fishers Ln.** Rm. **1061**

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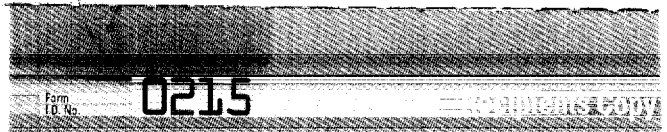
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Next business day

☐ **FedEx 2Day Freight**  
Second business day

☐ **FedEx 3Day Freight**  
Third business day

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Not available with  
FedEx First Overnight

☐ **HOLD Saturday**  
at FedEx Location  
Available for FedEx Priority  
Overnight and FedEx 2Day  
to select locations

Does this shipment contain dangerous goods?

One box must be checked.

☒ **No**

☐ **Yes**

As per attached  
Shipper's Declaration

☐ **Yes**

Shipper's Declaration  
not required

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Dry Ice, 9, UN 1845

x \_\_\_\_\_ kg

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Acct. No. in Section  
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☐ **Recipient**

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Total Weight

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By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

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